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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 082368-003300US |
| INTERNATIONAL APPLICATION NO. PCT/JP03/12075 | INTERNATIONAL FILING DATE September 22, 2003 | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/528,353 |
| TITLE OF INVENTION COMBINATION DRUG | | PRIORITY DATE CLAIMED September 26, 2002 |
| APPLICANT(S) FOR DO/EO/US Nobuyuki YASUDA and Kazuto YAMAZAKI | | |

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☒ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/528,353 | INTERNATIONAL APPLICATION NO. PCT/JP03/12075 | ATTORNEY'S DOCKET NUMBER 082368-003300US |
| 20. Other items or information: Express Mail Label No.: <u>EV 566969788 US</u> ; copy of references AC-AJ, AL and AM cited on the Information Disclosure Statement; Return copy of the Notification of Missing Requirements. | | |
| The following fees have been submitted | | CALCULATIONS PTO USE ONLY |
| 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300 | | \$ |
| 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200 | | \$ |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500 | | \$ |
| TOTAL OF 21, 22 and 23 = | | \$ |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) |
| - 100 = | /50 = | x \$250 |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ 130.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA |
| Total claims | - 20 = | x \$ 50 |
| Independent claims | - 3 = | x \$200 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | + \$360 |
| TOTAL OF ABOVE CALCULATIONS = | | \$ |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | \$ |
| SUBTOTAL = | | \$ |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ |
| TOTAL NATIONAL FEE = | | \$ |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | \$ |
| TOTAL FEES ENCLOSED = | | \$ 130.00 |
| | | Amount to be refunded: |
| | | \$ |
| | | Amount to be charged: |
| | | \$ 130.00 |

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- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 20-1430 in the amount of \$ 130.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 20-1430. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Kevin Bastian
TOWNSEND AND TOWNSEND AND CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, CA 94111-3834


SIGNATURE
Kevin Bastian
NAME
34.774
REGISTRATION NUMBER

60669744 v1



UNITED STATES PATENT AND TRADEMARK OFFICE

082368-003300US
KLB, SF

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|-----------------------------|-----------------------|------------------|
| 10/528,353 | Nobuyuki Yasuda | 082368-003300US |

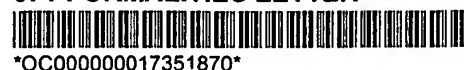
| INTERNATIONAL APPLICATION NO. |
|-------------------------------|
| PCT/JP03/12075 |

| I.A. FILING DATE | PRIORITY DATE |
|------------------|---------------|
| 09/22/2003 | 09/26/2002 |

20350
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

CONFIRMATION NO. 5028

371 FORMALITIES LETTER



Response Due 01/03/06

Date Mailed: 11/03/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/17/2005
- English Translation of the IA filed on 03/17/2005
- Copy of the International Search Report filed on 03/17/2005
- Copy of IPE Report filed on 03/17/2005
- Preliminary Amendments filed on 03/17/2005
- U.S. Basic National Fees filed on 03/17/2005
- Priority Documents filed on 03/17/2005
- Specification filed on 03/17/2005
- Claims filed on 03/17/2005
- Abstracts filed on 03/17/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

SKC

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

TAMALA D HOLLAND

Telephone: (703) 308-9140 EXT 209

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/528,353 | PCT/JP03/12075 | 082368-003300US |

FORM PCT/DO/EO/905 (371 Formalities Notice)